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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/572,946   | 11/20/2006  | Amit Gefen           | GEFENS              | 7525             |
| 1444 7590 04/02/2009<br>BROWDY AND NEIMARK, P.L.L.C.<br>624 NINTH STREET, NW<br>SUITE 300<br>WASHINGTON, DC 20001-5303 |             |                      |                     |                  |
| EXAMINER   |             |                      |                     |                  |
| ROBINSON, JAMES MARSHALL   |             |                      |                     |                  |
| ART UNIT   |             | PAPER NUMBER         |                     |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/572,946

**Applicant(s)**

GEFEN ET AL.

**Examiner**

James M. Robinson

**Art Unit**

3772

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 16-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 March 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-850)

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

Paper No(s)/Mail Date 09/06/2007

## **DETAILED ACTION**

### ***Priority***

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 158036, filed on 09/21/2003. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Drawings***

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the fitting element, cervical collar, restriction member, lock member, holes, dents, chin lift collar, and movable mover element must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering

of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claim 27 recites – chin lift collar – which is not disclosed in the specification. Claim 28 recites – movable mover element – which is not disclosed in the specification.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 29-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not provide support for

a jaw clasp member that comprises an airway protector. It appears from applicant's disclosure that the jaw clasp is an element of the airway protector. However, the noted claims appear to be limiting the jaw clasp as if it is a distinct invention, separate from the airway protector.

6. Claims 37 and 39-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The recitation – the airway protector as described in any of figures 1 to 32-- is not enabling. One of ordinary skill in the art would not be able select **any** of the figures and be able make/and or use the complete airway protector since some of the figures illustrate only a structural part, or single feature of the device.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 18-27, 29-37, and 39-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 18 recites the limitation "restrictor member" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claims 19-20 recites the limitation "the restrictor". There is insufficient antecedent basis for this limitation in the claim. Claims 18-20 recites the limitation "jaw

clasp. There is insufficient antecedent basis for this limitation in the claim. Claim 21 recites the limitation "rigid frame" in line 3. There is insufficient antecedent basis for this limitation in the claim. Claims 22-24 recites the limitation "rigid structure". There is insufficient antecedent basis for this limitation in the claim. Claim 21 recites the limitation "the rigid frame" in line 3. There is insufficient antecedent basis for this limitation in the claim. Claims 25-26 recites the limitation "said holes or dents" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claim 27 recites the limitation – or any other ingredients of the collar --. The limitation is vague and indefinite because one of ordinary skill in the art is unable to define the metes and bounds of the claim. Claims 29-36 recite the claim preamble – the jaw clasp --. The recitation renders the claim vague and indefinite because it is unclear if the claim is to a new independent jaw clasp alone or further limiting the airway protector of claim 27. Further, it appears claims 29-36 should depend from claim 28, which recites a jaw clasp in the preamble. In order to examine the claims, examiner, as best as can be understood from applicant's disclosure has examined claims 29-36 as if they were intended to further limit claim 28. With respect to claims 37 and 39-41 the recitation – the airway protector as described in any of figures 1 to 32 -- renders the claim indefinite. One of ordinary skill in the art is unable to define the metes and bounds of the claims.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 16-41 rejected under 35 U.S.C. 102(b) as being anticipated by Nagata et al. (US 5575763).

Nagata discloses a non invasive airway protector (1) useful for maintaining the airways in head and neck immobilized trauma patients open and for stabilizing the cervical spine, wherein said protector comprising a rigid motion- restricting frame (2) attached to said head, and two opposite mandible clasps (5) (right and left) being attached to the right and left sides of the mandible; each of said clasps is forming a 3-dimensional L- shaped fitting element (see fig. 2) adapted to specifically fit the L-shaped angle of the mandible comprising the horizontal body portion and the perpendicular Ramus portion, by a means of shape and size; further wherein said fitting elements are adapted to support said mandible, especially the body portion of the mandible and to enforce said body to move forwards and said Ramus to move downwards in relation to the maxilla; wherein the airway protector is a cervical collar (col 3 ln 24-27); additionally comprising a restrictor member (1b) restricting the motion or location of the jaw clasp relative to the rigid frame; wherein the restrictor (1b) limits the distance between the rigid frame and the jaw clasp; wherein the restrictor (1b) limits the direction of motion between the rigid frame and the jaw clasp; additionally comprising a lock member (10) preventing the backward motion of the jaw clasp relative to the rigid frame; wherein said rigid structure is formed essentially of one collar wrapped around the head and neck (col 3 ln 24-27); wherein said rigid structure is formed essentially of several parts (fig. 1)

connected together to fit a specific patient; wherein said holes (2b) or dents allow access to the ears of the patient (fig. 3a); wherein said holes or dents allow access to the front of the neck of the patient (fig. 6); additionally comprising a chin lift collar (1e) wherein holding point is the chin, gum, or any other member of the oral cavity; a jaw clasp (9) useful for performing the jaw-thrust maneuver motion of the jaw to maintain open airways comprising; a plurality of movable fitting elements (fig. 11) adapted to fit the jaw tightly; and, b. a plurality of movable mover elements (9a, 9b) adapted to move the jaw; additionally comprising at least one extrusion (1b) adapted to apply force against resistance of the muscles and to cause forward movement localized at both sides of the jaw; wherein the jaw-thrust maneuver motion is provided by a means of an adjustable knob (6) comprising an inside portion facing the angles of the mandible as holding points and an outside portion maneuverable by the care giver; wherein said inside portion of the adjustable knob comprising a rest (2c) and a bolt (9c), such that an accommodating-pushing groove (7) is provided; said accommodating-pushing groove (7) is adapted to concurrently accommodating the mandible angle while pushing it anteriorly towards the direction of the chin, i.e., in the opposite direction of cervical spin.

Nagata teaches all the elements of the claimed invention; see rejection above. The method for performing a device aided thrust maneuver would have resulted from the normal use of the airway protector including immobilizing the head of the patient (col 1 In 43-60); clasping the external portion of the mandible (col 2, In 35-48) by means of a airway protector; maneuvering said clasped mandible (col 3 In 49-60) forward and

slightly downward; in the manner that airway maintenance with cervical spin control is provided.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James M. Robinson whose telephone number is (571) 270-3867. The examiner can normally be reached on Mon-Fri 9AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571)272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James M. Robinson/

/Patricia Bianco/  
Supervisory Patent Examiner, Art Unit 3772  
03/30/09

